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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,037	02/09/2004	Paul G. Yock	13854.4004	1520

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EXAMINER	
MARVICH, MARIA	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,037	YOCK ET AL	
	Examiner	Art Unit	
	Maria B. Marvich, PhD	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is a reissue if United States Patent Number 6,346,098. Claims 20-100 have been added. Claims 8, 11, 15 and 19 have been amended. Claims 1-100 are pending in this application.

Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

Oath/Declaration

The reissue oath/declaration filed with this application is defective because it fails to contain the statement required under 37 CFR 1.175(a)(1) as to applicant's belief that the original patent is wholly or partly inoperative or invalid. See 37 CFR 1.175(a)(1) and see MPEP § 1414. The reissue oath must state that "The applicant believes the original patent **to be** wholly or partly...". The phrase "may be" cannot be used to replace the phrase "to be".

Claims 1-100 are rejected as being based upon a defective reissue oath under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175. Furthermore, applicants do not recite that each inventor has reviewed the claims and specification as amended, see CFR 1.63(b)(2).

The nature of the defect(s) in the oath is set forth in the discussion above in this Office action.

Information Disclosure Statement

Please provide an IDS listing all references in application 09/519,950 that appear on the face of US patent 6,346,098.

Specification

The disclosure is objected to because of the following informalities: in column 4, line 20 and 22, applicants incorrectly identify the described figure as Fig 1. However, the details most closely correlate with Figure 2. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10, 12-17, 20, 24, 28, 30-35, 36-46, 48-54, 56-58, 61-70, 72-82, 84-93 and 95-100 are rejected under 35 U.S.C. 102(e) as being anticipated by Makower et al (US 2002/0179098; see entire document).

Makower et al teach a method of locally administering an active agent such as blood, oxygen, autologous or xenograft tissue (which inherently comprise cells, peptides, proteins and nucleic acids) signal emitting targets or radiological imaging material (see e.g. paragraph 0012, 0048, 0097, 0109 and 0161) in which the agent is retroinfused into a vascular vessel such as a vein under conditions sufficient to disrupt the vein such that the agent enters interstitial space such as the myocardial space as recited in claims 1, 2, 3, 6, 8, 10, 12, 20, 37, 38, 39 and 42 (see e.g. paragraph 0097). Makower et al specifically teach methods of Transmyocardial Direct

Coronary Revascularization (TMDCR) in which a passageway-forming catheter is advanced through the coronary vein or artery and is used to create for example and interstitial passageways, which method function by creating pressure through the vessels as recited in claim 15, 44, 46 and 51 (see e.g. paragraph 0025 and 0026). As well, the catheter can have a tissue-penetrating element and a guidewire in the veins or arteries (see e.g. paragraph 0105). This interstitial passageway is thus generated by mechanical stress as recited in claims 7, 9, 30, 43, 45, 56-59, 61, 68, 72, 78, 79, 80, 82 and 84. To produce this passage, the vessel is distended or disrupted as recited in claims 13, 14, 16, 17, 36, 49, 50-54, 67, 69, 70, 81, 90-93 and 95 (see e.g. paragraph 0023). Further therapeutic applications are proposed such as installation of an apparatus or valves, thrombolysis, ablation (see e.g. paragraph 0029 and 0042) or insertion of imaging means or dyes (see e.g. paragraph 0048) as recited in claim 24.

In some embodiments, a delivery catheter is used to position a valve downstream of the site of administration (see e.g. figure 5b and paragraph 0137). The valve acts as an occlusion device as recited in claims 32, 34, 63, 65, 74, 76, 86, 88, 97 and 99. Alternatively a stent with an occlusion downstream of the site of administration as demonstrated in figure 8c would meet the limitations of the previously cited claims. As well the stent functions as a depot means carrying the cells as recited in claim 4 and 40. The method further comprises administration of energy to the vein such as heat as recited in claim 5 and 28, 41 (see e.g. claims 75 and 76). The specification does not define venous (veinous) branches in the specification. During prosecution, claims must be interpreted as broadly as their terms reasonably allow. As demonstrated in figure 12B, retroinfusion disrupts the venous branches upstream of the vessel as recited in claims 31,

35, 62, 66, 73, 77, 85, 89, 96 and 100. Furthermore, at least one upstream branch of the vessel can be occluded as recited in claims 33, 64, 75, 87 and 98.

Claims 1-3, 7-11, 13-19, 21-23, 29, 30-34, 36-39, 43-47, 49-59, 61-70, 72-82, 84-93 and 95-100 are rejected under 35 U.S.C. 102(e) as being anticipated by Wolff et al (US 6,867,196; see entire document).

Wolff et al teach methods of delivering nucleic acid to cardiac tissue using a channel leading to cardiac tissue from a vessel (vein or artery, see e.g. col 8, line 10-19), The instant specification defines interstitial space as the region or tissue beyond the wall of the vascular site or beyond the intimal space (see e.g. bridging paragraph col 3-4). The method involves a retrograde approach with increased permeability of the vessels as recited in claims 1, 2, 8, 10, 13, 14, 21-23, 30, 36-38, 54, 67, 69, 70, 72, 90-93 and 95 (see e.g. abstract, col 9, line 4-27 and col 11, line 1-65). Permeability of the vessel is increased by intravascular hydrostatic pressure as recited in claims 15-18, 44, 46, 49-53 (see e.g. col 11, line 1-55). This stress is proximal to the interstitial space and can be chemical (see e.g. col 11, line 34-54) as recited in claims 3, 29 and 39. As well, the stress can be mechanical as it is generated by clamping (see e.g. col 11, line 1-21) as recited in claims 7, 9, 43, 45, 56-59, 61, 68, 78-82 and 84. A catheter is used that has an occlusion device downstream of the site of administration of the agent (see e.g. figure 3) as recited in claims 32, 34, 63, 65, 74, 76, 86, 88, 97 and 99. As demonstrated in figure 4 and figure 3, the catheter comprises an occlusion device that is upstream and downstream of the site of administration. The specification does not define venous (veinous) branches. During prosecution, claims must be interpreted as broadly as their terms reasonably allow. Thus as

depicted in figure 4, the catheter would place an occlusion device such that at least one upstream branch of the vessel can be occluded as recited in claims 33, 64, 75, 87 and 98. This should necessarily result in disruption through increased permeability of the venous branches upstream of the vessel as recited in claims 31, 35, 62, 66, 73, 77, 85, 89, 96 and 100. Finally, Wolff et al teach that nucleic acids encoding cytokines can be delivered. Many cytokines are responsible for producing inflammatory responses. Thus it would be inherent that administration of cytokines would lead to production of inflammation in the vessels as recited in claims 11, 19, 47, 55, 60, 71, 83 and 94.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al (US 6,867,196; see entire document).

Applicants claim a method of locally administering an active agent to a host by retroinfusing said agent into the vessel under pressure of at least 50mm Hg, 60 mm Hg and 1000 mm Hg.

The teachings of Wolff et al are described above and are applied as before except;

Wolff et al do not teach that the pressure used during retroinfusion is at least 50mm Hg, 60 mm Hg and 1000 mm Hg.

It would have been obvious to someone of skill in the art to utilize pressure of at least 50mm Hg, 60 mm Hg and 1000 mm Hg in the method of Wolff et al given that the identification of these pressures would be required to optimize the hydrostatic pressure to permeabilize or disrupt the vessels for deliverance of the agents. A person of skill in the art would have been motivated to optimize these conditions to best utilize the methods of Wolff et al for deliverance of agents to interstitial spaces. The MPEP teaches "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages"). Given the teachings of the cited art and the level of skill of the ordinary skilled artisan at the time of the applicant's invention, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Conclusion

Claims 1-100 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen, PhD can be reached on (571)-272- 0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1633

August 12, 2005

DANIEL M. SULLIVAN
PATENT EXAMINER